K032139

APR - 5 2004

corgenix

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
REAADS von Willebrand Factor Activity Test Kit
March 31, 2004

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The REAADS von Willebrand Factor Activity Test Kit is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is Shield von Willebrand Factor Activity Kit (K000398) currently manufactured and marketed by Shield Diagnostics., Dundee, Scotland.

The REAADS von Willebrand Factor Activity Test Kit is an enzyme-linked immunosorbent assay (ELISA), utilizing the 96-microwell plate format, similar to the predicate device. Diluted patient plasma is incubated in the wells, allowing any available antigen to bind to the monoclonal antibody on the microwell surface. The plates are washed to remove unbound proteins or other plasma molecules. Bound antigen is quantitated using horseradish peroxidase (HRP) conjugated anti-human von Willebrand Factor detection antibody. Following incubation, unbound conjugate is removed by washing. A chromogenic substrate of tetramethylbenzidine (TMB) and hydrogen peroxide (H_2O_2) is added to develop a colored reaction. The intensity of the color is measured in optical density (O.D.) units with a spectrophotometer at 450nm. Patient von Willebrand Factor Activity in relative percent concentration is determined against a curve made from the reference plasma provided with the kit. The total incubation time (at room temperature) of the assay is 40 minutes.

The intended use of the device is for the quantitative determination of von Willebrand Factor Activity (vWF:Act) in citrated human plasma. The laboratory diagnosis of von Willebrand disease may require both quantitative and qualitative (functional) determinations to differentiate the two predominant subtypes of the disease, type I and type II. The classification of von Willebrand disease into subtypes is important in determining the course of clinical treatment.

Clinical studies demonstrate that REAADS von Willebrand Factor Activity Test Kit is safe and effective. These clinical studies also indicate that REAADS von Willebrand Factor Activity Test Kit and the Shield von Willebrand Factor Activity Kit are equivalent. A statistical evaluation of the entire group of clinical samples (n=262) was done to compare the two tests. Using the Pearson Product Moment Correlation statistical analysis, the correlation coefficient (r) demonstrates a positive correlation (r=0.943) and the P value (P<0.001) demonstrates a significant correlation of individual values between both populations.

Nanci Dexter
Director, Quality Assurance and Regulatory Affairs

2004-03-31
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 5 2004

Ms. Nanci Dexter
Director, Quality and Regulatory Affairs
Corgenix, Inc.
12061 Tejon Street
Westminster, CO 80234

Re: k032139
Trade/Device Name: REAADS von Willebrand Factor Activity Test Kit
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor deficiency Test
Regulatory Class: Class II
Product Code: GGP
Dated: March 4, 2004
Received: March 5, 2004

Dear Ms. Dexter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K032139

Device Name: REAADS von Willebrand Factor Activity Test Kit

Indications for Use:

The REAADS von Willebrand Factor Activity Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of von Willebrand Factor Activity (vWF:Act) in citrated human plasma.

The REAADS von Willebrand Factor Activity Test Kit is intended to be used by clinical (hospital and reference) laboratories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032139